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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,117	10/31/2003	William J. Bertrand	M190.247.101 / P0011522.0	8914

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EXAMINER	
DORNA, CARRIE R	
ART UNIT	**PAPER NUMBER**
3735	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/698,117	BERTRAND ET AL.	
	Examiner	Art Unit	
	Carrie Dorna	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *1-7 and 18-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 March 2010* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office action is responsive to the Amendment filed 23 March 2010. The Examiner acknowledges the amendments to claims 8 and 13. Claims 1-36 are now pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. **Claims 8, 10-13, and 15-17** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application No. 2002/0022793 (Bertrand et al.) in view of U.S. Patent No. 6,305,381 (Weijand et al.).

Regarding **claim 8**, Bertrand et al. teaches an electronic magnetic-based indicator tool comprising: a housing (*Figure 10, indicator central body,* 60) having a connection to a locator tool (*Figure 4, locator tool,* 26) (Indicator central body of the indicator tool is placed within the tube of the locator tool, [0059]); a compass module (*Figure 12, compass,* 62) for determining an orientation of sensed magnetic fields ([0053]; [0060]); and a locator tool interface (*Figure 9, index,* 88) communicating sensed magnetic field data to the user after receiving magnetic data values from the compass module (62) ([0058]; [0060]); wherein the locator tool (26) necessarily receives background magnetic field data (When the indicator tool is in use as part of the locator tool, the compass necessarily detects ambient magnetic fields.), receives target

magnetic field data when the indicator tool (*Figure 9, indicator tool,* 28) is located above an implanted flow control device having a magnetic indicator device (*Figure 1, magnet,* 20) coupled to a valve (*Figure 1, valve,* 10) ([0010]; [0060]), and determines a setting for the valve (10) within the implanted flow control device using the background magnetic field data and target magnetic field data ([0060]). Bertrand et al. does not teach that the indicator tool comprises an electronic processor.

However, Weijand et al. teaches an electronic magnetic-based indicator tool comprising: a housing having an electric connection to a locator tool (*Figures 1 and 4, array,* 3 and *processor,* 2) (col. 2, lines 44-47; col. 3, lines 17-19; see *Figures 1 and 4*; device necessarily has a housing containing an electrical connection between the array and processor); an electronic compass module (*Figures 1 and 4, antennas,* 30-32) for determining an orientation of sensed magnetic fields (col. 3, lines 31-35 and lines 43-52), wherein the electronic compass module comprises a target compass module and a background compass module (Ambient magnetic fields are necessarily detected by the array and processor if they are present. The target and background compass modules are considered part of the antennae 30-32 as these antennae necessarily detect any electromagnetic fields within the vicinity of the device, and send the sensed data to the processor, col. 3, lines 31-35 and lines 43-52); and a locator tool interface module (*Figure 4, switch,* 50, *amplifier,* 51, and *computer,* 53) for communicating sensed magnetic field data to a processing module (*Figure 4, microprocessor,* 54) in the locator tool (3 and 2) for receiving magnetic data values from the electronic compass module (30-32) (col. 3, line 56-col. 4, line 13); wherein the processing module (54) necessarily

receives background magnetic field data from the background compass module (Ambient magnetic fields are necessarily detected by the array and processor if they are present.); receives target magnetic field data from the target compass module when the indicator tool is located above an implanted device (*Figure 1, medical device,* 4) having a magnetic indicator device (*Figures 1 and 4, implanted coil,* 22) (col. 2, lines 44-50; col. 3, lines 31-35 and lines 43-52). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the mechanical indicator tool of Bertrand et al. to have an electronic detection and processing system for detecting the location and orientation of the magnetic field emitted by the implanted medical device similar to that of Weijand et al., because an electronic detection and processing system provides a noninvasive, automated mechanism which reduces the potential for human error in detecting the location and orientation of an implanted medical device.

Regarding **claim 10**, Bertrand et al. in view of Weijand et al. teaches all the limitations of claim 8. Bertrand et al. teaches that the indicator tool (*Figure 10, indicator tool,* 28) further comprises a mechanical key device (*Figure 10, ridge,* 70) about its housing for orientating the indicator tool (28) into a desired position relative to a locator tool (*Figure 4, locator tool,* 26) placed in a desired orientation relative to the implanted flow control device ([0054]; [0070]-[0071]).

Regarding **claim 11**, Bertrand et al. in view of Weijand et al. teaches all the limitations of claim 8. Bertrand et al. teaches that the indicator tool (*Figure 10, indicator tool,* 28) corresponds to a handheld device ([0014]).

Regarding **claim 12**, Bertrand et al. in view of Weijand et al. teaches all the limitations of claim 11. Bertrand et al. and Weijand et al. teach that the handheld device includes a removable battery (Weijand et al., *Figure 1, battery,* 21) (The battery is necessarily able to be removed from the remainder of the device, Weijand et al., col. 64-67).

Regarding **claim 13**, Bertrand et al. teaches an electronic magnetic-based indicator tool comprising: a housing (*Figure 10, indicator central body,* 60) having a connection to a locator tool (*Figure 4, locator tool,* 26) (Indicator central body of the indicator tool is placed within the tube of the locator tool, [0059]); a compass module (*Figure 12, compass,* 62) for determining an orientation of sensed magnetic fields ([0053]; [0060]); and a locator tool interface (*Figure 9, index,* 88) communicating sensed magnetic field data to the user after receiving magnetic data values from the compass module (*compass,* 62) ([0058]; [0060]); wherein the locator tool (*locator tool,* 26) necessarily receives background magnetic field data (When the indicator tool is in use as part of the locator tool, the compass necessarily detects ambient magnetic fields.); receives target magnetic field data when the indicator tool (*Figure 9, indicator tool,* 28) is located above an implanted flow control device having a magnetic indicator device (*Figure 1, magnet,* 20) coupled to a valve (*Figure 1, valve,* 10) ([0010]; [0060]); and determines a setting for the valve (*valve,* 10) within the implanted flow control device using the background magnetic field data and target magnetic field data ([0060]). Bertrand et al. does not teach that the indicator tool comprises an electronic processor.

However, Weijand et al. teaches an electronic magnetic-based indicator tool comprising: a housing having an electric connection to a locator tool (*Figures 1 and 4, array,* 3 and *processor,* 2) (col. 2, lines 44-47; col. 3, lines 17-19; see *Figures 1 and 4*; device necessarily has a housing containing an electrical connection between the array and processor); a target compass module (*Figures 1 and 4, antennas,* 30-32) for determining an orientation of sensed magnetic fields (col. 3, lines 31-35 and lines 43-52); a background compass module (*Figures 1 and 4, antennas,* 30-32) within the locator tool (3 and 2) (col. 3, lines 31-35 and lines 43-52); a locator tool interface module (*Figure 4, switch,* 50, *amplifier,* 51, and *computer,* 53) for communicating sensed magnetic field data to a processing module (*Figure 4, microprocessor,* 54) in the locator tool (3 and 2) for receiving magnetic data values from the target compass module (30-32) (col. 3, line 56-col. 4, line 13); wherein the processing module (54) necessarily receives background magnetic field data from the background compass module (Ambient magnetic fields are necessarily detected by the array and processor if they are present. The target and background compass modules are considered part of the antennas as these antennas necessarily detect any electromagnetic fields within the vicinity of the device, and send the sensed data to the processor.); receives target magnetic field data when the indicator tool is located above an implanted device (*Figure 1, medical device,* 4) having a magnetic indicator device (*Figures 1 and 4, implanted coil,* 22) (col. 2, lines 44-50; col. 3, lines 31-35 and lines 43-52). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the indicator tool of Bertrand et al. to have an electronic detection and processing system

for detecting the location and orientation of the magnetic field emitted by the implanted medical device similar to that of Weijand et al., because an electronic detection and processing system provides a noninvasive, automated mechanism which reduces the potential for human error in detecting the location and orientation of an implanted medical device.

Regarding **claim 15**, see discussion for claim 10.

Regarding **claim 16**, see discussion for claim 11.

Regarding **claim 17**, see discussion for claim 12.

4. **Claims 9 and 14** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application No. 2002/0022793 (Bertrand et al.) in view of U.S. Patent No. 6,305,381 (Weijand et al.) as applied to claims 8 or 13 above, and further in view of U.S. Patent No. 5,136,242 (Abraham-Fuchs).

Regarding **claims 9 and 14**, Bertrand et al. in view of Weijand et al. teaches all the limitations of claims 8 and 13 above. Bertrand et al. and Weijand et al. teach that the device necessarily detects background magnetic field data as well as target magnetic field data, but does not teach that the background data is subtracted from the target data to determine the true location and orientation of the sensed magnetic fields in the implant.

However, Abraham-Fuchs teaches a device for detecting the magnetic field emanating from a source in a patient's body comprising a processing module (*Figure 1, computer,* 9) subtracts measured background magnetic field data from measured target magnetic data to determine the location of the true target magnetic data (col. 1, lines

43-53; col. 2, lines 14-20 and lines 35-38; col. 3, lines 17-20). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the processing module of Bertrand et al. and Weijand et al. to subtract the background magnetic field data from the target magnetic field data to localize the target as taught by Abraham-Fuchs, because subtracting background magnetic field data from target magnetic field data prevents a false localization of the target magnetic field (Abraham-Fuchs, col. 3, lines 17-20 and lines 47-48).

Response to Arguments

5. Applicant's arguments filed 23 March 2010 have been fully considered but they are not persuasive. Applicant contends that it would not have been obvious to combine Bertrand and Weijand to teach the claimed invention, as Bertrand is directed to a manual system for magnetically determining the position and orientation of an implanted valve while Weijand is directed to magnetically determining the position of a drug reservoir.

In response to applicant's argument that Bertrand and Weijand are not combinable given their alleged difference in intended function, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Furthermore, both Bertrand and Weijand are directed to magnetically determining the position and orientation of an implanted medical device (see rejections above).

Therefore, the Examiner does not find these arguments persuasive, and the previous grounds of rejection have been maintained.

In response to applicant's argument based upon the age of the Abraham-Fuchs reference in comparison to that of the Bertrand and Weijand references, contentions that the reference patents are old are not impressive absent a showing that the art tried and failed to solve the same problem notwithstanding its presumed knowledge of the references. See *In re Wright*, 569 F.2d 1124, 193 USPQ 332 (CCPA 1977).

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carrie Dorna whose telephone number is (571) 270-7483. The examiner can normally be reached on Monday - Friday from 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner
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/C. D./
Examiner, Art Unit 3735